



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0906; FRL-9361-8]

#### Cyazofamid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of cyazofamid in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes several established tolerances that are superseded by tolerances established by this regulation. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0906, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the

telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: [nollen.laura@epa.gov](mailto:nollen.laura@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the Office of Chemical

Safety and Pollution Prevention (OCSPP) test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0906 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0906, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of December 8, 2011 (76 FR 76674) (FRL-9328-8), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7929) by IR-4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.601 be amended by establishing tolerances for residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile (CA), expressed as cyazofamid, in or on basil, dried leaves at 80.0 parts per million (ppm); basil, fresh leaves at 30.0 ppm; bean, succulent at 0.4 ppm; bean, succulent, shelled at 0.07 ppm; leafy greens, subgroup 4A at 9.0 ppm; vegetable, fruiting, group 8-10 at 0.40 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. Additionally, the notice requested that EPA remove the tolerances in 40 CFR 180.601 for residues of the fungicide cyazofamid and its metabolite CCIM, expressed as cyazofamid, in or on okra at 0.40 ppm; potato at 0.02 ppm; spinach at 9.0 ppm; and vegetable, fruiting, group 8 at 0.40 ppm, as they will be superseded by inclusion in crop group or subgroup tolerances. That notice referenced a

summary of the petition prepared on behalf of IR-4 by ISK Biosciences, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. The Agency has also determined that the time-limited tolerance on basil, fresh should be removed. The reasons for these changes are explained in Unit IV.D.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyazofamid including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyazofamid follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cyazofamid has a low order of acute toxicity via the oral, dermal, and inhalation routes of exposure. It produces minimal but reversible eye irritation, is a slight dermal irritant, and is a weak dermal sensitizer. In subchronic toxicity studies in rats, the kidney appeared to be the primary target organ, with kidney effects including an increased number of basophilic kidney tubules and mild increases in urinary volume, pH, and protein. However, no adverse kidney effects were noted in chronic toxicity studies in rats. There were no toxicity findings up to the limit dose in a subchronic toxicity study in dogs; in the chronic dog toxicity study, increased cysts in parathyroids were observed in males at the limit dose for chronic toxicity testing.

There were no maternal or developmental effects observed in the prenatal developmental toxicity study in rabbits and no maternal, reproductive, or offspring effects in the 2-generation reproductive toxicity study in rats. There was evidence of increased susceptibility following *in utero* exposure of rats in the prenatal developmental toxicity study at the highest dose tested; developmental effects, including an increased incidence of bent ribs, were observed in the absence of maternal toxicity.

There was no evidence of neurotoxicity or evidence of biologically relevant structural effects on the immune system in any study in the exposure database for cyazofamid. Skin lesions, which may be due to a systemic allergy, were observed in male mice in a carcinogenicity study. There was no evidence of carcinogenicity in the rat or mouse carcinogenicity studies and no evidence that cyazofamid is mutagenic in several *in vivo* and *in vitro* studies. Based on the results of these studies, EPA has classified cyazofamid as “not likely to be carcinogenic to humans.”

Specific information on the studies received and the nature of the adverse effects caused by cyazofamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document, “Cyazofamid. Human Health Risk Assessment for Proposed New Uses on Leafy Greens (Crop Subgroup 4A), Succulent-Podded and Succulent-Shelled Beans, Basil, Tuberous and Corm Vegetables (Subgroup 1C), and Fruiting Vegetables (Crop Group 8-10) with Updated Residential Risk Estimates of All Existing Residential Uses” at pp. 32-36 in docket ID number EPA-HQ-OPP-2011-0906.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which

no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level--generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)--and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

*<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.*

A summary of the toxicological endpoints for cyazofamid used for human risk assessment is shown in Table 1 of this unit. EPA notes that the last final rule for cyazofamid, published in the **Federal Register** of July 14, 2010 (75 FR 40745) (FRL-8833-1), included endpoints and points of departure for intermediate-term residential scenarios, including postapplication incidental oral exposure for children and dermal exposures for adults. However, the Agency has reevaluated these scenarios and has determined that residential exposure to turf and ornamentals is not likely to occur over an intermediate-term duration (i.e., 1 month to 6 months) for cyazofamid. Additionally, the Agency notes that the last final rule did not include an assessment of adult residential handler exposures. While the label for cyazofamid includes a statement that application by homeowners to residential turf is prohibited, it does not identify the product as a restricted use; therefore, a residential handler exposure assessment for short-term dermal



and inhalation exposures was performed to be protective of potential residential handler exposures.

**TABLE 1.--SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYAZOFAMID FOR USE IN HUMAN HEALTH RISK ASSESSMENT**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	An appropriate endpoint for a single exposure was not identified for the general population.		
Acute dietary (Females 13–49 years of age)	NOAEL = 100 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day  aPAD = 1.0 mg/kg/day	Rat Prenatal Developmental Toxicity Study. LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
Chronic dietary (All populations)	NOAEL = 94.8 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.948 mg/kg/day  cPAD = 0.948 mg/kg/day	18-Month Mouse Oral Carcinogenicity Study. LOAEL = 985 mg/kg/day based on increased skin lesions.
Incidental oral, short-term (1 to 30 days)	NOAEL = 30 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Rat Oral Toxicity Study. LOAEL = 295 mg/kg/day based on increased number of basophilic tubules of the kidneys, increased urinary volume, pH, and protein. This toxicity endpoint is also supported by the results of a 28-Day Oral Dose Range-Finding Study in rats. In this study, at 370 mg/kg/day or above increased incidence of basophilic tubules in the kidneys was found.

Dermal, short-term (1 to 30 days)	For children: No toxicity was found at 1,000 mg/kg/day in a 28-Day Dermal Toxicity Study; therefore, in the absence of hazard identified for this population, a dermal risk assessment is not necessary.		
	For adults: Dermal (or oral) study NOAEL = 100 mg/kg/day (dermal absorption rate = 37 %) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	Rat Prenatal Developmental Toxicity Study. LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
Inhalation, short-term (1 to 30 days)	Inhalation (or oral) study NOAEL = 100 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	Rat Prenatal Developmental Toxicity Study. LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
Cancer (Oral, dermal, inhalation)	Classification: “Not likely to be carcinogenic to humans” based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyazofamid, EPA considered exposure under the petitioned-for tolerances as well as all existing cyazofamid tolerances in 40 CFR 180.601. EPA assessed dietary exposures from cyazofamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. EPA identified

such an effect (increased incidence of bent ribs in the rat prenatal developmental toxicity study) for the population subgroup females 13 to 49 years old; however, no such effect was identified for the general population, including infants and children.

In estimating acute dietary exposure for females 13 to 49 years old, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994 to 1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, DEEM<sup>TM</sup> ver. 7.81 default processing factors and 100 percent crop treated (PCT) for all existing and proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994 to 1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues, DEEM<sup>TM</sup> ver. 7.81 default processing factors and 100 PCT for all existing and proposed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cyazofamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyazofamid. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Available environmental fate studies suggest cyazofamid is not very mobile and quickly degrades into a number of degradation products under different environmental conditions. Among the three major degradates for cyazofamid (CCIM, CCIM-AM, and CTCA), the two terminal degradates

are CCIM and CTCA. The highest estimated drinking water concentrations resulted from modeling which assumed application of 100% molar conversion of the parent into the terminal degradate CTCA. EPA used these estimates of CTCA in its dietary exposure assessments, a conservative approach that likely overestimates the exposure contribution from drinking water.

The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyazofamid and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyazofamid and its degradates. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of CTCA for acute exposures are estimated to be 136 parts per billion (ppb) for surface water and 2.18 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 133 ppb for surface water and 2.18 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 136 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 133 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cyazofamid is currently registered for use on turf at golf courses, sod farms, seed farms, college and professional sports fields, residential and commercial lawns, and on ornamental plants in landscapes and those grown in commercial greenhouses and nurseries. EPA assessed residential exposure using the following assumptions: For adult handlers, short-term dermal and inhalation exposures from mixing, loading, and applying cyazofamid in residential areas; for adults, short-term postapplication dermal exposure from contact with treated turf and ornamentals; and for children, short-term postapplication incidental oral exposure to treated turf, including hand-to-mouth activity, object-to-mouth activity, and soil ingestion. No POD was identified for dermal exposures to treated turf for children, since no toxicity was seen in the 28-day dermal toxicity study at the highest dose tested (1,000 milligrams/kilograms/day (mg/kg/day)); therefore, dermal postapplication exposure scenarios were not assessed for children. Based on the residential use profile, adult handler and adult and child postapplication exposures to cyazofamid are expected to be short-term only. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found cyazofamid to share a common mechanism of toxicity with any other substances, and cyazofamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyazofamid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for cyazofamid includes rat and rabbit developmental toxicity studies and a 2-generation reproductive toxicity study in rats. There was no indication of increased susceptibility, as compared to adults, of rabbit fetuses to *in utero* exposure in a

developmental study or of rat pups in the 2-generation reproduction study. There is evidence of increased quantitative susceptibility following *in utero* exposure of rats to cyazofamid in the prenatal developmental study; an increased incidence of bent ribs in fetuses at the highest dose tested was noted in the absence of maternal effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cyazofamid is complete except for immunotoxicity and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing (OCSPP Test Guideline 870.7800) and subchronic neurotoxicity testing (OCSPP Test Guideline 870.6200) for pesticide registration. However, the available data for cyazofamid do not show potential for immunotoxicity. Further, there is no evidence of neurotoxicity in any study in the toxicity database for cyazofamid. EPA does not believe that conducting neurotoxicity and immunotoxicity studies will result in a NOAEL lower than the regulatory dose for risk assessment. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional database uncertainty factor does not need to be applied.

ii. There is no indication that cyazofamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. Although there is evidence of increased quantitative susceptibility in the prenatal developmental study in rats, the Agency determined that concern is low because the developmental effect (increased bent ribs) is well identified with a clear NOAEL and LOAEL. In addition, other considerations indicating a low concern include the following: Increased bent ribs are considered a reversible variation rather than a malformation; the effect was noted only at the limit dose of 1,000 mg/kg/day and this endpoint was used to establish the a RfD for females 13-49; and the overall toxicity profile indicates that cyazofamid is not a very toxic compound. Therefore, there are no residual concerns regarding developmental effects in the young.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyazofamid in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyazofamid.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.



1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyazofamid is not expected to pose an acute risk. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyazofamid will occupy 2.5% of the aPAD for females 13 to 49 years old, the population group of concern for acute effects.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyazofamid from food and water will utilize 1.5 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyazofamid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cyazofamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyazofamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,200 for children 1-2 years old and 390 for adults. Because EPA's level of concern for cyazofamid is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, cyazofamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for cyazofamid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyazofamid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyazofamid residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate analytical methodology is available to enforce the proposed tolerances. Cyazofamid and the metabolite CCIM are completely recovered (>80% recovery) using the Food and Drug Administration's (FDA) Multi-Residue Protocol D

(without cleanup). In addition, a high performance liquid chromatography/ultraviolet detector (HPLC/UV) method is available for use as a single analyte confirmatory method.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for cyazofamid.

#### *C. Response to Comments*

EPA received comments from a private citizen to the notice of filing for cyazofamid, PP# 1E7929, objecting to the establishment of tolerances associated with the petition. In addition, the commenter noted several adverse effects seen in animal toxicology studies for cyazofamid and claims because of these effects no tolerance should be approved.

EPA has found, however, that there is a reasonable certainty of no harm to humans after considering these toxicological studies and the exposure levels of humans to cyazofamid. The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by FFDCA section 408 states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

#### *D. Revisions to Petitioned-For Tolerances*

Based on the data supporting the petition, EPA revised the proposed tolerances on several commodities, as follows: Basil, dried leaves from 80 ppm to 90 ppm; bean, succulent from 0.4 ppm to 0.5 ppm; bean, succulent shelled from 0.07 ppm to 0.08 ppm; leafy greens subgroup 4A from 9.0 ppm to 10 ppm; and vegetable, fruiting, group 8-10 from 0.40 ppm to 0.9 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. Additionally, the Agency has determined that the time-limited tolerance on basil, fresh at 12 ppm should be removed, as it will be superseded by the permanent tolerance on basil, fresh leaves.

### **V. Conclusion**

Therefore, tolerances are established for residues of cyazofamid, 4-chloro-2-cyano-*N*, *N*-dimethyl-5-(4-methylphenyl)-1 *H*-imidazole-1-sulfonamide, and its

metabolite, 4-chloro-5-(4-methylphenyl)-1 *H* -imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on basil, dried leaves at 90 ppm; basil, fresh leaves at 30 ppm; bean, succulent at 0.5 ppm; bean, succulent shelled at 0.08 ppm; leafy greens subgroup 4A at 10 ppm; vegetable, fruiting, group 8-10 at 0.9 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. This regulation additionally removes the established permanent tolerances on okra, potato, spinach, and fruiting vegetable group 8, and the time-limited tolerance on basil, fresh because these tolerances are superseded by new crop group or subgroup tolerances established by this action.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 12, 2012.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*



Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.601:

- a. Remove the commodities “Okra”, “Potato”, “Spinach”, and “Vegetable, fruiting, group 8” from the table in paragraph (a).
- b. Add alphabetically the following commodities to the table in paragraph (a).
- c. Remove the commodity “Basil, fresh” from the table in paragraph (b).

The additions read as follows:

**§ 180.601 Cyazofamid; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Basil, dried leaves	90
Basil, fresh leaves	30
Bean, succulent	0.5
Bean, succulent shelled	0.08
* * *	* * *
Leafy greens subgroup 4A	10
* * *	* * *
Vegetable, fruiting, group 8-10	0.9
Vegetable, tuberous and corm, subgroup 1C	0.02

\* \* \* \* \*

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